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| 09/831,233 | 09/14/2001 | Stephen M. Allen | BB1129 | 1413 |
| 7590 02/04/2004 E I du Pont de Nemours & Company Legal Patents Wilmington, DE 19898 | | | EXAMINER BUI, PHUONG T | |
| | | | ART UNIT 1638 | PAPER NUMBER |
| DATE MAILED: 02/04/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/831,233

Applicant(s)

ALLEN ET AL.

Examiner

Phuong T. Bui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-56 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 42-56 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7/9/01.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Restriction election

1. The Office acknowledges the receipt of Applicant's amendment and restriction election filed December 5, 2003. Applicant elects Group 1 and Invention A (SEQ ID NO:1 encoding SEQ ID NO:2) without traverse. Claims 42-56 are pending and are examined in the instant application. This restriction is made FINAL.

Sequence Listing

2. Applicant's CRF and paper sequence listing have been entered. However, upon examination of SEQ ID NO:1 and its corresponding amino acid sequence SEQ ID NO:2, it is unclear what region of SEQ ID NO:1 encodes SEQ ID NO:2. Clarification is required.

Information Disclosure Statement

3. An initialed and dated copy of Applicant's IDS form 1449 filed July 9, 2001 is attached to the instant Office action.

Claim Rejections - 35 USC § 112, second paragraph

4. Claims 42-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 42, line 5, "one of" should be deleted, as there is only one sequence set forth. In claims which recite "Clustal V method of alignment", it is unclear whether "Clustal V method of alignment" is the same as "Clustal method of alignment" disclosed in the specification. In claim 54, line 3, "an expression vector" should be amended to "the expression vector" for proper dependency.

Clarification and/or correction are required.

Claim Rejections - 35 USC § 101 Utility

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 42-56 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility. In the claims, Applicant asserts SEQ ID NO:2 has ornithine acetyltransferase activity. However, Table 4 (p. 23) of the specification shows SEQ ID NO:2 has 72.9% sequence identity to a glutamine amidotransferase, the closest prior art. Applicant disclosed no conserved domains, working examples, or evidence to support the functional recitation of "ornithine acetyltransferase" in the claims. Accordingly, it would appear that SEQ ID NO:2 is a glutamine amidotransferase and not an ornithine acetyltransferase.

Furthermore, the claimed invention does not meet the utility requirements under current utility guidelines because Applicant does not disclose that SEQ ID NO:1 encodes a complete protein; and SEQ ID NO:1 does not appear to contain a complete open reading frame since it does not begin with the start codon methionine. Neither Applicant's disclosure nor the state of the prior art at the time the invention was made provides guidance as to where the catalytic domain of Applicant's ornithine acetyltransferase is located. No empirical data are presented to verify that SEQ ID NO:1 or a nucleotide sequence encoding SEQ ID NO:2 encodes a protein having ornithine acetyltransferase activity. While empirical data are not required, sequence

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alignment is generally useful in placing a protein in a particular class but does not replace verification of function. Here, the sequence alignment also does not support that SEQ ID NO:1 encodes an ornithine acetyltransferase. Since SEQ ID NO:1 encodes a partial protein and does not contain the catalytic domain(s) necessary for enzymatic function, the utility for such a sequence would be lacking. It would also follow that sequences having 85-95% sequence identity to SEQ ID NO:2 would also lack utility for the same reasons.

Additionally, there also is no well-established utility for SEQ ID NO:1 and a sequence encoding SEQ ID NO:2. SEQ ID NO:1 does not have a well-established utility for hybridization purposes because the encoded protein does not have utility for the reasons indicated above. Thus, for the reasons set forth, the claimed sequences lack utility (see Utility Examination Guidelines published in Federal Register/ Vol. 66, No. 4/ Friday, January 5, 2001/ Notices; p. 1092-1099).

Claim Rejections - 35 USC § 112, first paragraph

7. Claims 42-56 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Additionally, claims reciting less than 100% sequence identity are not enabled because they encompass unspecified base deletions, additions, substitutions, and combinations thereof while retaining ornithine acetyltransferase activity. While skilled in the art can readily make base changes, further guidance is necessary as to what changes would be tolerated.

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Claim 54 is not enabled because Applicant's polynucleotide would not complement any histidine biosynthetic auxotroph, but would only complement one which is deficient in ornithine acetyltransferase, if Applicant's polynucleotide in fact encodes ornithine acetyltransferase. Multiple enzymes are involved in histidine biosynthesis; and as they are structurally distinct and perform different functions from each other, they are not interchangeable with each other and cannot complement auxotrophs deficient in another enzyme. Accordingly, the claimed invention is not enabled.

8. Claims 42-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. Applicant is invited to point to the page and line number in the specification where "ornithine acetyltransferase" can be found. Absent of such support, Applicant is required to cancel the new matter in response to this Office action.

9. Claims 42-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. The claims are drawn to an isolated polynucleotide comprising a nucleotide sequence encoding a polypeptide having at least 85% sequence identity to SEQ ID NO:2.

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However, the translated amino acid sequence SEQ ID NO:2 appears to be only a partial sequence of a protein (see utility rejection above). SEQ ID NO:1, which encodes SEQ ID NO:2, is only a partial gene sequence and does not contain a complete open reading frame encoding a complete protein. However, the “comprising” language in the claims reads upon complete gene sequences having in common a nucleotide sequence encoding SEQ ID NO:2. There is insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine the complete structure of a gene encoding an ornithine acetyltransferase based upon the disclosure of a partial sequence, absent further guidance. Accordingly, one skilled in the art would not recognize from Applicant’s disclosure of SEQ ID NO:1 that Applicant is in possession of the complete gene encoding a complete ornithine acetyltransferase.

The claims reciting 85-95% sequence identity lack adequate written description because Applicant does not disclose a representative number of species as encompassed by these claims. The claims encompass mutants and allelic variants and thus imply that structural variants exist in nature, yet no structural variant has been disclosed. The claims also encompass ornithine acetyltransferases from other species. The implication is that there is a gene and a protein other than that disclosed which exists in nature, but the structure thereof is not known. Applicant discloses a single sequence SEQ ID NO:1 isolated from *Impatiens balsamia*. Thus, there is insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine such mutants, allelic variants and ornithine acetyltransferases from other plants and organisms, absent further guidance. Accordingly, there is lack of adequate description

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to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/ Vol.66, No. 4/ Friday, January 5, 2001/ Notices; p. 1099-1111.

Remarks

10. No claim is allowed. SEQ ID NO:1 and a nucleotide sequence encoding SEQ ID NO:2 are free of the prior art. It is understood by the Office the recited Clustal V alignment method uses the default parameters set forth on page 9, lines 30-32 of the specification. The closest prior art teaches a glutamine amidotransferase from *Arabidopsis thaliana* having 72.9% sequence identity with SEQ ID NO:2 at the amino acid level (Table 4, p. 23).

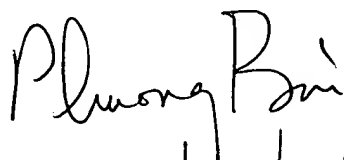
11. Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Bui whose telephone number is (571)272-0793.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (571)272-0804.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Phuong Bui
Primary Examiner
Art Unit 1638
January 29, 2004


1/29/04